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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,753	12/19/2001	Jayarama K. Shetty	GC695	2084

7590 03/24/2004

Genencor International, Inc.  
925 Page Mill Road  
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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/24/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/026,753

Applicant(s)

SHETTY ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

The amendment filed February 5, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-52 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 102/103***

Claims 46-52 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)).

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The reference discloses a liquefied starch product which appears to be identical to the presently claimed strain, based on the fact that the prior art product is a starch liquefact having the same DE as recited in the claims, produced by an enzyme having essentially the same hydrolytic properties as the enzyme recited in the claims. See, e.g., page 14. It is noted that the claims have been amended to require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, the fact remains that the claims recite a product made by contacting the same starting material as the prior art, with the enzyme as the prior art. Consequently, even if the process

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results in the desired product more quickly, the claimed liquefied starch product still appears to be anticipated by the reference.

It is noted that the enzyme used to produce the claimed product is from a different species of microorganism than the prior art enzyme. However, even if this results in a nominal difference between the reference product and the claimed product such that there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would have expected nominal differences between starch liquefact products based on normal process variations between different hydrolysis batches and differences in enzyme batches. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Regarding the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture

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products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

### ***Claim Rejections - 35 USC § 103***

Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through

-----Biotechnology, Genencor International, Inc., (1998)) in view of -----  
JP 10-136979.

Shetty discloses a process of preparing glucose from starch, said process using the claimed process parameters. See, e.g. pages 6 and 14. Shetty differs from the claims in that Shetty uses a different  $\alpha$ -amylase enzyme than that recited in the claims. However, Shetty discloses that  $\alpha$ -amylases active at acidic pH are advantageous in processes of producing glucose from starch. Specifically, the liquefaction step is improved by decreasing chemical demand for pH adjustment, reducing color and by-product formation, and lowering refining requirements and

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costs (Shetty, page 7). Also, the lower pH afforded by the use of acidophilic  $\alpha$ -amylase eliminates the undesirable formation of maltulose (Shetty, page 8). Shetty also discloses that enzymes which do not require calcium or stability are advantageous, as are relatively thermostable enzymes. Shetty, page 11, last sentence. ("It is evident from the above data that an improved thermostable alpha-amylase which can operate at a pH below 6.0 and at lower or no calcium will significantly reduce refining costs and improve the final glucose yield.")

As is evident from the English abstract, JP '979 discloses an  $\alpha$ -amylase which meets exactly the criteria disclosed by Shetty as being desirable and advantageous for use in the

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disclosed process of preparing glucose from starch.

Specifically, the enzyme is thermostable, acid-stable, optimally active at a pH of about 4, and does not require calcium for activity (see Table 2). Thus, the artisan of ordinary skill practicing Shetty's process clearly would have recognized that the enzyme disclosed by JP '979 possesses all the properties required for use in Shetty's process. The artisan of ordinary skill would therefore clearly have been motivated to have used the enzyme of JP '979 in Shetty's process. A holding of obviousness is therefore required.

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It is noted that neither reference appears to disclose the use of the claimed amount of amylase. However, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that the rate of the liquefaction would have been readily optimized, depending on the amount of enzyme used. Thus, the claimed amounts of enzyme must be considered obvious in view of the fact that enzyme concentration was known to be a result-effective parameter, and therefore routinely optimized by artisan of ordinary at the time of applicant's invention.

Lastly, it is again noted that the claims have been amended to require the DE of about 10-12 to be reached within 60-75 minutes of adding the amylase. However, it is respectfully submitted that the new claim language does not serve to distinguish the claims from the cited prior art. Specifically, it is noted that at 75 minutes the DE of the various liquefaction processes disclosed by Shetty is about 9, which is encompassed by the lower limit of the presently claimed DE range of "about 10-12." See page 14 of Shetty, especially figs. 2 and 3. Thus, viewing the cited prior art, it is respectfully submitted that the artisan of ordinary skill had a reasonable expectation that the claimed DE could be reached in the claimed

amount of time by following the teachings of Shetty. A holding of obviousness is therefore required.

***Response to Arguments***

All of applicant's argument has been fully considered but is not persuasive of error. As discussed above, the new language requiring the DE of about 10-12 to be reached in about 60-75 minutes does not appear to distinguish the product recited in claims 46-52 from the prior art. While the claims may encompass a process quicker than that in the prior art, on the current record applicant has provided no evidence demonstrating any difference between the product made in the prior art and the product recited in the claim. Product claims 46-52 must therefore remain rejected.

With respect to process claims 1-45, it is again noted, as discussed above that the language DE of "about" 10-12 encompasses the slightly lower DE values present in the figures on page 14 of the Shetty et al reference. It is therefore respectfully submitted that, contrary to applicant's argument, the claims remain sufficiently broad to encompass processes suggested by the prior art. While it is noted that applicant's Figure 4 appears to demonstrate an unexpectedly rapid and therefore advantageous liquefaction process with respect to the



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KSTM enzyme, applicant's current claim language is much broader than this apparent showing of an unexpected result. The holding of obviousness must therefore be maintained.

No claims are allowed. Note that the provisional obviousness-type double patenting rejection over copending application 10/026,288 has been withdrawn in view of the abandonment of that application.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action  
is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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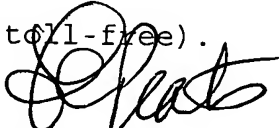
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

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(PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Francisco C Prats  
Primary Examiner  
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FCP